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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/655,935

Applicant(s)

GAFNER ET AL.

Examiner

Michele Flood

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4,6 and 7 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on May 1, 2006.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

This application contains Claims 8-19 drawn to an invention nonelected with traverse on May 26, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-4, 6 and 7 are under examination.

Response to Arguments

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. 102(b), a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue*, 766 F.2d 531, 533, 266 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose each limitation of the claimed invention, *MEHL/Biophile*

Int'l Corp. v. Milgram, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the functions of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejections - 35 USC § 102

Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated Hutchens (U). Applicant's arguments have been fully considered. However, the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth herein.

Applicant argues case law asserting that the Examiner has misapplied the inherency doctrine; and, thereby Applicant concludes that the teachings of Hutchens do not anticipate the instantly claimed subject matter. For example, on page 5 of Applicant's 'Remarks and Response', third paragraph, bridging page 6, first paragraph, Applicant argues, "As directed by the courts, inherency 'cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is

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later established." Nonetheless, the Office notes an apparent omission of the word

'Obviousness' in Applicant's version of the court's dicta:

As stated in MPEP 2141.02 (section styled, "Disclosed Inherent Properties Are Part Of 'As A Whole' Inquiry), "Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993)."

With further regard to the facts of *In re Rijckaert*, please review the following:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). >Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.<

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d

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1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Hence, the facts in *In re Rijckaert* are not analogous to the facts and the establishment of inherency made by the Examiner in the previous Office action because the aforementioned cited case law is predicated on the prediction of obviousness of a claimed invention based on inherency of what is not known at the time an invention is made versus anticipation based on inherency of what limitations are either expressly disclosed or inherently disclosed by the prior art with regard to the claimed invention. Therefore, Applicant's are not found persuasive because, on page 174, Column 1, under "DOSE", Hutchens teaches an extract of *Scutellaria laterifolia* (also known as *Scutellaria lateriflora*): "DOSE: Tincture alone, 3-12 drops in water as indicated. As an intrusion [apparent misspelling of infusion], 1 teaspoonful of the cut or powdered herb steeped in 1 cupful of boiling water for ½ hour; take every 3-4 hours for adults; in proportion for children."

Contrary to Applicant's argument, the Examiner did not apply the doctrine of inherency based "on what would result due to optimization of conditions" to establish the

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anticipation of the claimed subject matter made under 35 U.S.C. 102(b) by the teachings of Hutchens. Clearly, the Examiner provided sufficient basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Applicant is invited to revisit the previous Office action wherein on page 3, the Examiner set forth the terms and the reasoning for rejecting the instantly claimed subject matter based on inherency with regard to the anticipatory teachings of Hutchens (and set forth below for convenience).

‘Hutchens does not expressly teach that the reference extract comprises each of the claim-designated flavonoids having the claim-designated percent amount by weight. However, the plant source material and the ingredients used in the making of the plant extracts taught by Hutchens are one and the same as instantly disclosed by Applicant. Thus, the claim-designated flavonoids having the claim-designated percent amount by weight are considered inherent to the extract of *Scutellaria laterifolia* taught by Hutchens.’

Applicant further argues, “The Applicants contend that the instant invention provides novel compositions and process for making those compositions that are not, as determined by the dicta of the courts cited above, inherent in the prior art because the compositions and concentrations, as claimed, were not known or inherent in the prior art.” However, Applicants’ arguments are not persuasive because of the foregoing case law:

“There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only

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that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed. Cir. 1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.")>; *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate)<."

Also, it is not the obviousness of the composition itself which is at issue here.

What is at issue here is the anticipation of the instantly claimed product-by-process composition because the claim language of the claims defines a product-by-process, rather than a method/process of using the composition or making for the composition itself *per se*. Please note the following:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or

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unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id.*< See also **MPEP § 2112.01** with regard to inherency and product-by-process claims and **MPEP § 2141.02** with regard to inherency and rejections under **35 U.S.C. 103**.

Given that the claims before us are directed to the product and not the method of isolation, and given that Hutchens teaches a product-by-product composition prepared from the one and the same plant source material, solvent and experimental processing conditions disclosed by Applicant as being useful in preparing an extract of *Scutellaria lacteriflora* L., and given that Applicant has not shown that the claim-designated flavonoids or concentrations thereof are not present in the prior art composition, the claim-designated flavonoids having the claim-designated percent weight amount are considered inherent to the prior art composition, absent sufficient and convincing evidence to the contrary (such as a side-by-side comparison that the instantly claimed product-by-composition differs from the product-by-process taught by Hutchens).

Based on the foregoing, the Office believes that the anticipatory rejection based on inherency is proper given that Applicant has not provided a clear and convincing argument that the instantly claimed product-by-process is an act of invention rather than mere observation.

The rejection anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1-4 and 6-7 remain rejected under 35 U.S.C. 102(b) as anticipated by Hutchens (X) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hutchens (X) in view of Green et al. (U), and further in view of Sheu et al. (V), Wang et al. (8, Planta Med, 2002. 66(4): 535-537. Benziodizepine binding site-Structure-activity relationships of flavonoids isolated from *Scutellaria baicalensis* root.), and Charaux et al. (W). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

Applicant claims an extract made by a process comprising: combining dried *Scutellaria lateriflora* L. plant material with a water solution; heating said solution to at least 70°C; and separating solid material from said solution after a predetermined period, whereby said extract has a content of flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside lateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight. Applicant further claims the extract of claim 1 having a content of baicalin of at least 8-9% by weight. Applicant claims a process for obtaining an extract of *Scutellaria lateriflora* L. rich in flavonoids, said process comprising: combining dried *Scutellaria lateriflora* L. plant material with a water solvent to form a solution; heating said solution to at least 70°C; and separating solid material from said solution after a predetermined period, whereby said extract has a content of flavonoids calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I,

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lateriflorin, baicalein, lateriflorein and wogonin, of at least 18% by weight. Applicant further claims the process of claim 3 wherein said solution is boiling water. Applicant further claims the process of claim 3 further comprising stirring the solution for a predetermined period; and, further comprising drying said extract.

On page 174, Column 1, under “DOSE”, Hutchens teaches an extract of *Scutellaria laterifolia* (also known as *Scutellaria lateriflora*: “DOSE: Tincture alone, 3-12 drops in water as indicated. As an intrusion [apparent misspelling of infusion], 1 teaspoonful of the cut or powdered herb steeped in 1 cupful of boiling water for ½ hour; take every 3-4 hours for adults; in proportion for children.”

The claims are drawn to an extract of *Scutellaria lateriflora* L. rich in claim-designated flavonoids in an amount of at least 18% by weight and having a content of baicalin of at least 8-9% by weight; and, a method of making thereof comprising claim-designated process steps, ingredients, process steps and experimental parameters. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicant's main argument is directed to the idea that the Examiner has not pointed to some motivation to combine the references to establish a *prima facie* case of obviousness to arrive at the instantly claimed invention.

While Applicant's arguments have been fully considered, they are not found persuasive because the primary teachings of Hutchens were relied upon for the reasons set forth in the previous Office action and for the reasons set forth immediately above. Because the composition taught by Hutchens appears to be identical to the presently claimed composition; and, therefore Hutchens is considered to anticipate the claimed product-by-process composition for the following reasons: Although Hutchens does not expressly teach that the referenced extract has a content of flavonoids calculated as the sum of the claim-designated flavonoids in amount of at least 18% by weight, the Office deems that the extract taught by Hutchens comprises the instantly claimed ingredients in the amount claimed by Applicant, since the plant source, the boiling water solution, the process steps of extraction, and the experimental parameters for the process steps of extraction are the same or essentially the same, as instantly claimed by Applicant; and, thus, the result effect for obtaining an extract of *Scutellaria lateriflora* L. having flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I,

lateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight; and, an extract having a content of baicalin of at least 8-9% by weight is considered inherent to the extract and the process of making the plant extracts taught by Hutchens. The referenced process of making the composition taught by Hutchens also appears to be identical to the presently claimed process of obtaining the claim-designated plant extract and is considered to anticipate the claimed process for the following reasons: Although Hutches does not expressly teach the instantly claimed process step for separating solid material from the solution after a predetermined period and stirring the solution for a predetermined period, it is generally assumed in the art that the preparation of a plant extract includes the instantly claimed process steps, as evidenced by Green, on page 109, under "*HOT INFUSION*"; and, the process of making the composition taught by Hutchens encompasses the same or essentially the same plant source, the boiling water solution, the process steps of extraction, and the experimental parameters for the process steps of extraction, as instantly claimed by Applicant; and, thus, the result effect for obtaining an extract of *Scutellaria lateriflora* L. having flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I, lateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight; and, an extract having a content of baicalin of at least 8-9% by weight is considered inherent to the extract and the process of making the plant extracts taught by Hutchens. Consequently, the claimed composition and the process of making thereof appear to be anticipated by the reference, absent evidence to the contrary.

In the alternative, even if the claimed composition and method of making thereof are not identical to the teachings of Hutchens with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed inventions particularly in view of the similar characteristics which they have been shown to share, e.g., the plant source, the boiling solution, the process steps of extraction, and the experimental parameters for the process steps of extraction are the same or essentially the same, as disclosed by Applicant. Thus, the claimed composition and the claimed process of making thereof would have been obvious to those of ordinary skill in the art within the meaning of USC 103. For instance, while Hutchens clearly teaches combining dried plant material of *Scutellaria lateriflora* L. with boiling water to form a solution, Hutchens is silent to the instantly claimed process step for separating solid material from the solution after a predetermined period and stirring the solution for a predetermined period. However, it would have been obvious to one of ordinary skill in the art to employ the instantly claimed process steps into the making of the composition taught by Hutchens to provide the instantly claimed inventions because at the time the invention was made the claim-designated process steps were known as conventional in the preparation of a plant extract. For example, on page 109, under "*HOT INFUSION*", Green teaches a method of making a hot infusion comprising combining dried plant material with boiling water, stirring the solution, and heating the solution for a predetermined time, and separating solid material from the solution. Moreover, it would

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have been obvious to one of ordinary skill in the art to obtain an extract of *Scutellaria lateriflora* L. having a content of flavonoids by using the instantly claimed ingredients, solvents, process steps and experimental parameters to provide the instantly claimed inventions because at the time the invention was made it was known in the art of herbal extraction to use the instantly claimed process steps to obtain flavonoids from dried plant material of a species of *Scutellaria*, as evidenced by the teachings of Sheu, Wang and Charaux. Firstly, Sheu teaches a method for obtaining various flavonoids from the plant material of a *Scutellaria* plant, *i.e.*, baicalin (I), baicalein (II), wogonin (III) by extraction with water or water/methanol or ethanol. Sheu further teaches that the content of baicalin was dependent on the source of the plant material. For example, Sheu teaches, "The price of the crude drugs is proportional to the content of I but not related to II and III. The content of I, the most important biologically active component of *Scutellariae* root, in boiling water extracts of the wine-moistened samples is higher than that in extracts of untreated crude drugs by about 30%. However, it was lower when the samples were extracted with organic solvents. When the samples were soaked in water, the I content of the crude drugs decreased markedly (about half remained after 9 h soaking) but this had no effect on that of the processed samples. The processing of *Scutellariae* can effectively prevent the decomposition of I and increases its rate of extraction boiling water." Secondly, Wang teaches a method for obtaining various flavonoids from the plant material (roots) of a *Scutellaria* plant by extracting the plant material with an organic solvent and then with boiling water three times, and concentrating the extract to dryness. In another instance, Wang teaches

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obtaining various flavonoids from the plant material (leaves) of a *Scutellaria* plant by extracting the plant material with water and then concentrating the extract. Wang further teaches that the water solution was chromatographed on a macroporous resin with various organic solvents, such as alcohol to determine the flavonoid content of the extract. Thirdly, Charaux teaches a method for the extraction of baicalin in leaves of *Scutellaria* by extracting fresh leaves with hot water and acidifying while hot. One of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to provide the instantly claimed extract employing the instantly claimed process steps for obtaining an extract of *Scutellaria lateriflora* L. rich in flavonoids because at the time the invention was made it was well known in the art that the instantly claimed source of plant material, process steps, solvents, and experimental parameters for the extraction of flavonoids from plant material of the claim-designated plant, such as the plant material taught by Hutchens, were beneficial in the extraction of flavonoids. Thus, the instantly claimed extract and the method of making thereof would have been *prima facie* obvious and a matter of optimization to provide a result effect variable to one of ordinary skill in the art practicing the invention at the time the invention was given the references before him. Furthermore, references in conventional result-effective work conditions (*e.g.*, ingredients concentrations or order of process steps, length of process, *etc.*) do not support the patentability of claimed subject matter, unless there is clear and sufficient evidence indicating such working condition(s) is/are critical. Where the general conditions of a claim are disclosed in the

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prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" (see, e.g., MPEP 2144.05).

Given that the claims before us are directed to a product-by-product composition and a method of making thereof, and given that Hutchens teaches a product-by-product composition prepared from the one and the same plant source material, solvent and experimental processing conditions disclosed by Applicant as being useful in preparing an extract of *Scutellaria lacteriflora* L.; and given that Green teaches a method of making a hot infusion comprising combining dried plant material with boiling water, stirring the solution, and heating the solution for a predetermined time, and separating solid material from the solution, such as the *Scutellaria lacteriflora* L. extract taught by Hutchens; and given that flavonoids were known to be inherent to water extracts of the claim-designated plant material, such as the *Scutellaria lacteriflora* L. extract taught by Hutchens, as evidenced by the teachings of Sheu, Weng, and Charaux; and given that Applicant has not shown that the claim-designated flavonoids or concentrations thereof are not present in the prior art composition, the claim-designated flavonoids having the claim-designated percent weight amount are considered inherent to the prior art composition, absent sufficient and convincing evidence to the contrary (such as a side-by-side comparison that the instantly claimed product-by-composition differs from the product-by-process taught by Hutchens); and, thereby anticipated, if not *prima facie* obvious in view of the combined prior art teachings.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note, "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
July 3, 2006